## 9-AMINOCAMPTOTHECIN WITH DILUENT

## NSC - 603071

Chemical Name: 9-Amino-20-(S)-camptothecin

Other Names: 9-AC

CAS Registry Number: 91421-43-1

Molecular Formula:  $C_{20}H_{17}N_3O_4$  M.W.: 363.4

Stability: Intact vials are stable for 5 years at room temperature (22-25 °C). Intact vials are stable for at least one year when stored at elevated temperature (50 °C).

When constituted as directed, the solution exhibits no decomposition in 48 hours at room temperature (22-25 °C) or in 7 days under refrigeration (2-8 °C). Use within six hours is recommended.

**NOTE:** Acivicin solutions exhibit very fine particles and/or very light haze under high intensity light. The particulate burden is very low, and formulated lots have met USP criteria for particulate matter. The lots are essentially free of visible particulate matter. Nevertheless, as a precaution, it is recommended that the constituted solution be filtered through a  $0.22~\mu$  filter prior to injection. Filtration does not reduce the drug content.

Further dilution to a concentration of 0.05 mg/mL in 5% Dextrose in 0.9% Sodium Chloride Injection, USP results in a solution which exhibits no decomposition in 48 hours at room temperature.

A 10 mg/mL solution of acivicin in amino acid injection (Aminosyn®, Abbott) showed no physical or chemical changes over a two-week observation period.

Route of Administration: Intravenous

## **Upjohn's Product:**

**How Supplied**: For injection, 25 mg, vial: supplied as a lyophilized powder with 39.45 mg of mannitol, USP, and 24 mg of citric acid in 10 mL flint vials.

**Solution Preparation**: 25 mg/vial: When constituted with 5 mL of Sterile Water for Injection, USP, each milliliter contains 5 mg of acivicin, 7.89 mg of mannitol, USP, 4.8 mg of citric acid and sodium hydroxide to adjust the pH to approximately 5.2.

Storage: Store the intact vials at room temperature.

## **NCI's Product:**

How Supplied: For injection, 25 mg, vial: supplied as a lyophilized powder with 25 mg of mannitol, USP in 10 mL flint vials.

**Preparation:** When constituted with 5 mL of Bacteriostatic Sodium Chloride Injection, USP, containing benzyl alcohol, the resulting solution contains 5 mg/mL of acivicin, and 5 mg/mL of mannitol, USP, at pH 3.5-6.5.

Storage: Store the intact vials at room temperature.